Joint Research Management Office Standard Operating Procedure for:			
Queen Mary Ethics of Research Committee application and approval procedure			
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Purpose and scope

This Standard Operating Procedure (SOP) outlines the general administration and management of applications and amendments to the Queen Mary Ethics of Research Committee (QMERC) for research ethics approval, which provides a robust review of research, but is risk adapted to enable a proportionate review of low-risk research.

The procedure is applicable to everyone carrying out research involving human participants, human tissue samples or personal data under the auspices of Queen Mary, whether their current place of work is within or outside University premises. This includes, but is not limited to, all staff and registered students.

The QMERC does not review the following:

(1) Research studies recruiting National Health Service (NHS) patients as participants, analysing NHS patient data or taking place in the premises of NHS Trusts: such applications will be processed by the JRMO research governance team (research.governance@qmul.ac.uk) and will require ethical review by an NHS REC.

(2) Evaluation studies, however, this exemption does not apply: where the evaluation will lead to results that are generalisable and/or creating new knowledge; to evaluation studies involving potentially vulnerable human participants (for example, children) and/or the data is considered

to be sensitive or confidential in nature; or if researchers plan to publish their results, as many journals require evidence of ethical approval. The QMERC may also review evaluation studies where ethical review is a requirement of the funding body.

(3) The secondary analysis of data collected from human participants if all of the following apply: the data is completely anonymous; the data is not considered to be sensitive or confidential in nature; if researchers can evidence that consent from the data controller has been obtained to access the data; if the researchers can evidence that consent for reuse of data for research purposes was provided by the human participants.

Ethical approval cannot be granted retrospectively. Where research has commenced without first obtaining QMERC approval, the application will be invalidated and may be referred for further investigation, including the policy on research misconduct investigation (SOP 33), as appropriate.

More details on the QMERC application and review process, as well as guidance documents and further support can be found on the JRMO website: http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/

Abbreviations:

GDPR	General Data Protection Regulation
HRA	Health Research Authority
JRMO	Joint Research Management Office
NHS	National Health Service
PI	Principal Investigator
Queen Mary	Queen Mary University of London
QMERC	Queen Mary Ethics of Research Committee
REC	Research Ethics Committee
SOP	Standard Operating Procedure

Definitions:

Research
"The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies." (Source: Health Research Authority (HRA)).

Audit
A project designed to assess a service against a standard, e.g. 'does this service meet a predetermined standard?' It does not involve randomisation, generalisation or allocation to an intervention.

Service Evaluation
Evaluates a service but is not generalisable to other services and does not compare to a standard. It does not involve randomisation, generalisation or allocation to an intervention.

Review Panel
The process that standard applications (of moderate/high risk) go through to obtain QMERC approval; a Review Panel referring to an in-person or virtual meeting of a sub-committee of the 'main' QMERC.

Low-risk application review
The process that low-risk research studies (such as those that do not involve vulnerable participant groups and negligible risk of harm to researchers and participants) go through in order to obtain QMERC approval; the application is not reviewed at Review Panel or main QMERC meeting.

QM Ethics of Research Committee (main QMERC)
A Committee of Senate comprising of QMERC Chair, Deputy Chair and Chairs of Review Panels.

Personal data
"Any information relating to an identified or identifiable person ('data subject'). An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person" (Art.4 GDPR).

Pseudonymised data
Where a link exists between the research data and the individual who provided it. To reduce the risk of disclosure, the researcher uses methods such as storing the participant's name or other identifiers separately from the research data; or replacing the participant's name and other identifiers with a unique code and using this code to refer to the participant data. Coding the data does not make that data anonymous under the General Data Protection Regulation (GDPR).

Anonymous
Data are fully anonymised if no one, including the researcher, can connect the data to the individual who provided it. No direct personal identifiers are collected, for example names, addresses or student identification numbers.

Minor Amendments
Amendments that require minimal/no changes to the materials to participants; they might include reasonable and justifiable time extensions; additional named researchers to the study team; increased/decreased participant sample size; error corrections in text, and other minor changes.

Major Amendments
Amendments that involve a significant change to methodology and, as such, generally (but not always) require a significant change to the materials to participants, for example they might include; additional methods of data collection; significant changes to recruitment methods; additional types of participant interaction and additional participant groups etc.

Relevant SOPs:	
SOP 13a	Barts Health /Queen Mary Sponsorship of Research Studies – Process for researchers
SOP 33	Investigation and resolution of research misconduct allegations

SOP Text:		
Preparing and submitting a new application for QMERC review		
	Responsibility	**Activity**
1.	Principal Investigator (PI) / Supervisor	**Determine whether a study requires QMERC review** QMERC approval is a requirement of the Queen Mary Policy on Research with Human Participants (Appendix 1). Advisory QMERC opinion is required for research studies taking place at international sites, under the auspices of Queen Mary, in addition to the REC approval in the country of the proposed research site.

		Failure to obtain QMERC approval before the research study begins is a non-compliance and places researchers at risk of possible disciplinary action and research misconduct investigation.
2.	PI / Supervisor / Students	**How to apply for QMERC review** Researchers must complete the relevant QMERC application form (Associated Document 1) and submit this to the Research Ethics team (research-ethics@qmul.ac.uk). The researcher should declare in the application form whether the study is eligible for the low-risk or Review Panel route; depending on the nature and the risks of the study. The Economic and Social Research Council provides examples of the types of ethical issues than can increase risk levels in research. The Research Ethics Facilitator will confirm eligibility of the selected review route. Submission deadlines apply to applications qualifying for Panel review, as they are subject to in-person or virtual meetings of the QMERC.
3.	PI / Supervisor / Student	**Writing a high standard research ethics application** Researchers should familiarise themselves with QMERC specific requirements regarding wording in participant information and consent forms, QM Policies on data storage, retention and disposal and other related guidance. Information and guidance for completing and submitting a research ethics application form and templates for writing Participant Information Sheets (PIS) and Consent Forms (Associated Document 2 and 3) and what constitutes a minimum application pack is available on the QMERC website. To avoid delays the researcher should ensure a complete application and all the necessary documents are submitted.
4.	Supervisor	**Authorise student research ethics application** For supervisor responsibilities please review the guidance on the QMERC website. Supervisors must counter-sign the QMERC research ethics application form for student studies prior to applications being submitted.
After submitting a new research ethics application for QMERC review		
5.	Research Ethics Facilitator (or delegated other)	**Review, acknowledge, record and check application** The Research Ethics Facilitator will ensure that all applications qualifying for QMERC review will be processed and approved as per the present standard operating procedure. Studies sitting outside QMERC will be triaged accordingly. The Research Ethics Facilitator will acknowledge receipt of the application, record this on the appropriate database, and screen for compliance with Queen Mary Policy on Research with Human Participants, and any other applicable policies. The Facilitators will also provide an initial review and provide recommendations for improvement of the application supporting documentation, thereby increasing the likelihood of QMERC approval.

		In addition to low-risk and Review Panel routes, review by the Main Committee of QMERC may be required, depending on the nature and risk level of the study. Dates of the Main QMERC meetings are available on the QMERC website.
6.	Research Ethics Facilitator (or delegated other)	**Establish whether 'dual review' (sponsorship by the JRMO) is applicable** Dual review is applicable if the research involves heightened risk to the institution and/or participant; a novel or invasive research intervention; additional indemnity and sponsorship; or if JRMO liaison is required to ensure regulatory compliance. The researcher will be informed at the earliest possible opportunity if Queen Mary sponsorship is required. Decision to be taken by the Facilitator, with early engagement with colleagues in the Governance section of the JRMO via the usual practice for Governance Officer allocation (research.governance@qmul.ac.uk).
QMERC: Low-Risk Application Review		
7.	Research Ethics Facilitator (or delegated other)	**Provide independent review of individual low-risk studies** The Research Ethics Facilitator has a responsibility to provide independent review to low-risk individual studies that qualify for the QMERC low-risk review route, and to ensure that ethical review decisions are appropriately recorded and reported to QMERC. Researchers submitting individual studies will not be invited to attend a formal meeting and the outcome of the review will be sent to the researchers via email.
QMERC: Low-Risk Generic Applications		
8.	All	**Process for overarching generic approvals** Researchers have the option of applying for a 'generic approval' to provide over-arching ethical approval to cover a group of low-risk, sufficiently similar studies. The application for 'generic approval' will be initially screened by Facilitators and submitted to the next available Review Panel or a specially-arranged Chairs Panel. The generic approval represents a two-stage review; the first at central QMERC-level and the second at School or Department level, ensuring the study is eligible to sit under the scope of the generic approval, confirming it is low-risk and any ethical issues mitigated. Generic approvals are subject to the usual Amendment process and require renewal every 3 years (see post approval section below).
QMERC: Review Panel		
9.	Research Ethics Facilitator (or	**Provide administrative support to QMERC Review Panels**

	delegated other)	An agenda will be prepared in advance for each Review Panel meeting, which will include at least the following: date, time and venue (or online platform if the meeting will take place virtually); applications for ethical review to be considered at the meeting; lead reviewers for each application. Documents for the QMERC Review Panel meetings will be distributed to members by the Research Ethics Facilitators as soon as the agenda is finalised and no later than one week prior to the meeting. Invite PIs, students and their supervisors, to the review meeting.
10.	PI (or delegated other) / Supervisor / Student	**Review Panel meeting attendance** The PI or delegated other will be invited to attend the Review Panel meeting in person or be available via telephone or videoconference at the time of the review, whether the meeting is held in person or virtually. Attendance in person or via an alternative means is strongly encouraged so that any queries or concerns from the QMERC Review Panel members are resolved at the meeting. For student applications, the Supervisor or delegated representative should attend the meeting. QMERC reserves the right to postpone the review of any application where the supervisor (or appropriate delegate) is not available to support the student.
11.	QMERC Panel members	**Providing independent review to studies from across the Faculties and promoting a culture of best research ethics practices across the University.** The main purpose of the role of Review Panel member is to conduct ethical review of applications that qualify for Panel review, and to bring specific expertise to the ethics review process from the Faculty the member represents. For more information and the role description for Review Panel members, please see our website and the related QMERC terms of reference (Appendix 3).
12.	Research Ethics Facilitator (or delegated other)	**Facilitate QMERC Panel Review** The Research Ethics Facilitator(s) will attend Review Panel meetings; record the attendance of members, ensuring that the meeting is quorate; record the minutes of the discussion and compose written outcome of the application review. At the meeting, the Facilitator will advise members of compliance with any relevant legislation. After the meeting, the Facilitator will assist with the administration of any further review that is required. The opinion of the QMERC Review Panels on each application for ethical review is detailed in termly reports to the Main Committee of the QMERC.
13.	Research Ethics Facilitator (or delegated other)	**Inform PI of QMERC Review Panel decision** A Review Panel decision letter, or email correspondence seeking further clarification between Research Ethics Facilitator and researcher, will take place within 10 working days following a convened meeting. The Research Ethics Facilitator will assist applicants with the submission of revised documents in the case of Conditional Approval or additional review. See the website for QMERC decision options.

14.	Principal Investigator	**Comply with the decision of QMERC, and ensure that all conditions set by QMERC are fully met prior to commencing study** A response to a Conditional Approval is requested within 3 months of date of issue. If no response is received within 6 months, QMERC will withdraw the Conditional Approval and the study will require a new application.
15.	Research Ethics Facilitator (or delegated other)	**Issue Approval Letter to PI via email** Issue approval letter using the QMERC template, including any specific conditions and the standard terms of approval. Ethical approval is issued for a duration of three years as standard. Save the approval letter in the appropriate electronic storage folder and update the status of the application on database.
Post research ethics approval responsibilities		
16.	PI / Supervisor	**Submit an Amendment** Submit a letter or e-mail addressed to the Chair of QMERC, but submitted to the Facilitator by e-mail (research-ethics@qmul.ac.uk), quoting the QMERC Reference Number and PI name, outlining the nature of the amendment, explaining what ethical considerations, if any, are raised by the proposed amendment and how these ethical considerations will be addressed, including any revised and tracked-changed documentation as applicable. The maximum number of Amendments that may be submitted during the lifetime of the study duration and the ethics approval, outside of exceptional circumstances, is limited to three major and three minor amendments per study.
17.	Research Ethics Facilitator (or delegated other)	**Review amendment** Acknowledge receipt of the application, record on the relevant database, and screen for continued compliance with Queen Mary policies. Research Ethics facilitator will review amendment and confirm that the proposed changes do not alter the original application so significantly as to warrant NHS REC review, a change in its risk classification or a new application to the QMERC. Inform JRMO Governance staff of Amendment outcome if dual review was originally undertaken and provide final versions of any amended supporting documents if appropriate.
18.	Research Ethics Facilitator (or delegated other)	**Process the Amendment for review** To review the details of the Amendment and consider whether the Amendment should be classified as minor or major. If the possible impact is unclear, liaise with the Chair of QMERC with regard to the assessment of the proposed amendment as either a major or a minor Amendment. If it is a low-risk study (or a minor Amendment to a standard application), Facilitators to conduct ethical review of the submitted Amendment, seeking

		further information from researchers where necessary. Mindful that any amendment to a study that was originally classified as low-risk, may change the study's classification and may subsequently require review by a Review Panel. If the amendments are otherwise insignificant requests with minor changes and minimal impact, Amendments to be approved by the Research Ethics Facilitator, with the Chair/lead reviewer of original Panel informed for information only. If it is a major amendment to a standard application, Facilitator to liaise with the Panel Chair and/or the lead reviewer of the original application and the researcher with regard to approving the amendment via Chair's Action. If it is a major or minor Amendment to an application that was reviewed by the Main Committee of the QMERC, the Amendment will be reviewed by QMERC Chair.
19.	Research Ethics Facilitator (or delegated other)	**Inform PI of QMERC decision** Ensuring any new terms of the approval are explicit in the approval letter; and that the approval letter is saved and stored in a secure place, along with the original approval letter. If not approved, send an e-mail to the PI detailing the reasons why the Amendment was rejected, and the suggested changes that could be made in submitting a successful Amendment application.
20.	PI	**Comply with the decision, working to ensure any conditions are fully met before implementing the changes detailed in the Amendment.**
21.	PI	**Submitting Annual Progress Reports (APR) and End of Study Notification** An APR form (Associated Document 4) should be completed and submitted to the Facilitator on the anniversary of the date on the QMERC approval letter, and no later than 15 months following approval; and every year thereafter, until completion. APR is not a requirement for those studies that commence and complete within one year of the QMERC approval, nor is it applicable for low-risk studies. Notification of the end of study, including final reports where possible, are required for all studies. The PI should complete the QMERC End of Study Notification Form (Associated Document 5) and submit to the Facilitator within three months of the completion of the study. APR and End of Study Notification Forms are only a requirement for applications that received approval letters dated 1st January 2020 and after.
22.	Research Ethics Facilitator (or delegated other)	**Receive and process APRs, End of Study Notification Forms and final reports** Liaise with the QMERC Chair as appropriate should any unexpected issues be reported by researchers. Any reports declaring unexpected issues will be returned to the original Review Panel that reviewed and advised ethical approval. Other reports that declare no unexpected events or issues will be recorded on the database and stored in application file.
Data Storage and Management		

23.	Research Ethics Facilitator (or delegated other)	**Processing, filing and storage of application data** All files and notable correspondence relating to an application will be stored securely on the QMERC research ethics shared drive/approved QM cloud storage; with a central database maintained for all applications. Files will be retained for 10 years, as per the Queen Mary Records Retention Schedule, with special arrangements made for files concerning research with children (20 years). At this point data will be confidentially destroyed (physical files) or deleted (electronic records). Metrics on all QMERC applications are reported to JRMO senior management and Queen Mary Senate, with a copy of QMERC Main Committee meeting paperwork retained securely by Queen Mary archivist staff.

Change control

This section outlines changes from version **4.0** to version **5.0**

Section changed	Summary and description of changes
16	Change to the number of amendments within the lifecycle of a study

List of Associated Documents *(these are standalone documents)*

Associated Document 1a	QMERC Research Ethics Application form
Associated Document 1b	QMERC Research Ethics Application form – DDS-approved version
Associated Document 2a	QMERC Participant Information Sheet template
Associated Document 2b	QMERC Participant Information Sheet template – DDS-approved version
Associated Document 3a	QMERC Consent Form template
Associated Document 3b	QMERC Consent Form template – DDS-approved version
Associated Document 4	QMERC Annual Progress Report Form
Associated Document 5	QMERC End of Study Notification Form

Appendices

1. Queen Mary Policy of Research with Human Participants
2. Queen Mary Policy on Research Integrity
3. QMERC Terms of Reference

Related Queen Mary Policies and Documents

- JRMO QMERC website: http://www.jrmo.org.uk/performing-research/conducting-research-with-human-participants-outside-the-nhs/
- Data Protection Policy
- Queen Mary Health and Safety Policy
- Queen Mary Joint Policy on Research Misconduct
- Queen Mary Strategy 2030
- Research Management Policy
- Risk Assessment Guidance and Forms
- Code of Practice for Research Degree Programmes

Key legislations and regulations

- Data Protection Act (2018)
- Human Tissue Act (2004)
- Information Commissioner's Office: Guide to the GDPR

Other external bodies guidelines

- UK Data Service
- UK Research Integrity Office – Recommended Checklist for Researchers
- UK Research Integrity Office – Code of Practice for Research
- Universities UK – The concordat for research integrity